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Serial No.: 10/805,576

REMARKS

Claims 1-41 are pending in this application. Claims 2, 8, 14 and 32 have been withdrawn from consideration. These claims are eligible for rejoinder in accordance with the provisions of MPEP 800.

The subject matter of claim 4 has been inserted into claims 12 and 20. Support for the additional amendments to claims 1, 12 and 20 can be found, for example, in paragraph [0053] of the specification.

Support for new claims 35-39 and 41 is found, for example, in paragraphs [0008], [0034], [0053] and [0075]-[0080] of the specification as well as Figs. 3A-3E.

Support for new claim 40 is found in original claim 5.

New claims 35-41 read on the elected species.

No new matter has been added.

Claim 31 has been allowed.

Rejection in view of Bates et al. and Sheu et al.

Claims 1, 3-7, 9-13, 15-30, 33 and 34 have been rejected under 35 U.S.C. 103 as being unpatentable over Bates et al. 6,530,951 (Bates) in view of Sheu et al. 5,837,377 (Sheu). This rejection is respectfully traversed.

The examiner has relied on the embodiment of Bates illustrated in Figures 8-10D. In this regard, there is disclosed a metal substrate 14 with depressions or wells 28 and 28' and coating layers 16 and 20. The wells 28 and 28' may contain a therapeutic agent.

The coating layers disclosed are not polyelectrolytes and there is no criticality to their composition except that layer 20 must be porous. In fact the various coating layers may be formed from the same polymer. See, for example, col. 20, lines 42-64.

There is no suggestion in this reference to use the polyelectrolyte layers of the instant claims, much less a multilayer coating region like that currently claimed.

There is no disclosure of ceramic substrates.

Sheu discloses medical articles, generally contact lenses, having polyelectrolyte coatings for the purpose of rendering them hydrophilic. The article comprises a "substrate", an "ionic polymer layer" and a "disordered polyelectrolyte coating". The coating must include at least one

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infiltrating or intermixed polyelectrolyte. See, for example, column 1, line 59, to column 2, line 19. An example of what is meant by infiltrating is given at col. 8, lines 1-8, in which the polymeric layer is a hydrogel polymer or copolymer and the solvent system is chosen to cause the polymeric layer to swell, thereby allowing one or more polyelectrolytes to penetrate or infiltrate the polymeric layer. Sheu does not teach or suggest a polyelectrolyte multilayer coating region wherein each polyelectrolyte layer has a net charge opposite in sign from the adjacent layers. For example, although at least one polyelectrolyte must have a charge opposite to the ionic polymeric layer, col. 1, lines 51-53, Sheu further teaches that two or more polyelectrolytes of different charge may be intermixed, see, e.g., col. 1, lines 59-61, which may render the polyelectrolyte coating and the ionic polymer layer of the same overall charge.

The differing nature of the polyelectrolyte coating of Sheu from the polymer layers of Bates and the present claims is specifically illustrated at column 7, lines 31-33, of Sheu, where it is disclosed that consecutive polyelectrolytes layers, each having the same charge, can be deposited from solution.

Ceramic substrates are broadly disclosed in Sheu, but there is no disclosure of any type article that could utilize a ceramic substrate.

The Office has urged that it would have been obvious to modify the material property of the polymeric cover of Bates with the polyelectrolyte material of Sheu in order to create a more versatile, biocompatible surface capable of being adsorbed by water.

Sheu, however, teaches that these "ionically bonded" coatings are resistant to changes in pH, elevated temperatures, exposure to detergents or organic solvents, mechanical stress, abrasion and repeated ultrasonic washings. See, col. 3, lines 21 *et seq.*

Furthermore, in Bates, a porous polymer layer is used to carefully control the release rate of an underlying bioactive material over both the short and long terms. See, e.g., col. 7, lines 46-48. In order to permit careful control of the release rate, Bates teaches that the porous polymer layer is deposited over the bioactive material, rather than dispersing the bioactive material within or through it. Bates, col. 13, lines 1-6. If the device of Bates were modified in accordance with the teachings of Sheu, however, the addition of an ionic polymeric layer and a disordered polyelectrolyte coating, which structure is noted in Sheu to be very stable, would interfere with that control.

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Furthermore, there is nothing in the references themselves to suggest that one of ordinary skill in this art would have been motivated to make the articles of Bates more hydrophilic or to make them using ceramic substrates (see claim 12).

Accordingly, to arrive at the subject matter presently claimed would require, at the very least, undue hindsight of the type proscribed by precedent. See, merely for example, *Akso N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985). See also MPEP 2142, second paragraph.

Moreover, even with the use of such hindsight, the combination would not result in the here-claimed invention. Neither of the references teaches a multilayer coating region in which *each* polyelectrolyte layer has a net charge opposite in sign from the adjacent layers as currently claimed. See above discussion of Sheu.

Moreover, neither reference teaches a biodisintegrable polyelectrolyte multilayer coating region as claimed in claims 4, 12, 20 and 30. Indeed, the disordered polyelectrolyte coating of Sheu is quite stable, resistant even to changes in pH, elevated temperatures, exposure to detergents or organic solvents, mechanical stress, abrasion and repeated ultrasonic washings.

A biodisintegrable polyelectrolyte multilayer coating region as currently claimed is beneficial in that one is eventually left with a bare ceramic or metallic structure sequent. As noted in paragraph [0004], metallic and ceramic structures are robust, resulting in excellent resistance against mechanical damage. Moreover, they are frequently more biologically inert than polymers, and in some cases are bioactive. Furthermore, metallic and ceramic structures can be made porous, thereby enabling them to hold large amounts of drugs.

To summarize, there is no suggestion or reasonable motivation to combine the two reference teachings, and their combination would not result in the here-claimed invention. Thus, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. 103 are respectfully requested.

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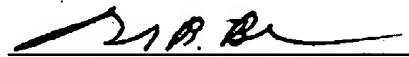
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Conclusion

In view of the above, Applicant submits that pending claims 1-41 are in condition for allowance. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

All fees due and owing in respect to this Amendment may be charged to deposit account number 50-1047.

Respectfully submitted,



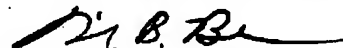
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